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National Cancer Program

Report of the National Cancer Advisory Board

1981

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
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This report of the National Cancer Advisory Board (NCAB) for Fiscal Year 1981, from October 1980 through September 1981, is presented in accordance with the provisions of the National Cancer Act of 1971 (P.L. 92-218) and Amendments of 1974 (P.L. 93-352).

Table of Contents

INTRODUCTION

I. RECOMMENDATIONS AND ACTIONS OF THE NCAB IN FY 1981

II. NCI REORGANIZATION AND PERSONNEL CHANGES

III. NCI BUDGET

IV. NATIONAL CANCER PROGRAM REAUTHORIZATION

V. NCAB'S RELATIONSHIP WITH THE DIVISIONAL BOARDS OF SCIENTIFIC COUNSELORS

VI. REVIEW OF NCI CONTRACTS AND GRANTS

VII. FREDERICK CANCER RESEARCH FACILITY

VIII. ENVIRONMENTAL CARCINOGENESIS AND PREVENTION

IX. CANCER CENTERS

X. ADDITIONAL REPORTS AND TOPICS OF INTEREST

XI. NCAB MEMBERSHIP AND ACTIVITIES

XII. PRESIDENT'S CANCER PANEL MEMBERSHIP AND ACTIVITIES

APPENDIX I and II

INTRODUCTION

The National Cancer Advisory Board (NCAB) is concerned with both the content and management of the National Cancer Program (NCP). Among its principal concerns this year were policy and administration of the Institute's contracting procedures. The Board wishes to go on record as strongly supporting the vigorous efforts of the Director, Dr. Vincent T. DeVita, Jr., to resolve these long-standing problems in a most effective way. Testimony describing the role of the Board and its support for the NCP was delivered by the NCAB Chairman (Dr. Henry Pitot) in May before the Senate Labor and Human Resources Subcommittee on Investigations and General Oversight. The members of the National Cancer Advisory Board welcome any opportunity to share their knowledge and experiences of the National Cancer Program with the Congress and the Administration.

This year the Board continued to advise the National Cancer Institute (NCI) Director and his staff on the major reorganization of the Institute and witnessed final approval of this reorganization by the Secretary of the Department of Health and Human Services (DHHS). In addition to these changes in the Institute, the Board and NCI staff had to grapple with many complex problems resulting from an ever-tightening budget and a shrinking staff. They also have dealt with many issues: reauthorization of the National Cancer Program, NCAB's interaction with the Boards of Scientific Counselors, review of NCI contracts and grants, management of the Frederick Cancer Research Facility, environmental carcinogenesis and prevention, and revision of guidelines for cancer center support (core) grants. The Board also had the pleasure of welcoming Dr. Vincent T. DeVita as the Director of NCI.

The major issues resolved by the Board in FY 1981 are summarized in the next Section. The rest of this report describes the deliberations and changes within the National Cancer Program on which the issues are based.

New technique of nucleotide sequencing allows scientists to read DNA's genetic code, base pair by base pair. The technique is of fundamental importance in exploring the differences between normal and cancer cells.

I. RECOMMENDATIONS AND ACTIONS OF THE NCAB IN FY 1981

October

The Board adopted the following general policies concerning core grants for cancer centers (revised guidelines for these were then drafted by the Board of Scientific Counselors of the new Division of Resources, Centers, and Community Activities):

- The NCI should continue to support multidisciplinary programs, and there should be diverse organizations and different categories of centers.
- Centers should be allowed to change both their category or their program emphasis to maintain flexibility.
- The core grants should serve as a support mechanism for the research activities of cancer centers.

The Board also adopted these specific policies regarding core support:

- Support should be provided for: activities that consolidate and focus cancer-related research efforts; salaries of selected cancer staff; the operation of central shared resources and services; and administration. All other center activities should be required to depend on extra-NCI funding mechanisms.

The Board made these recommendations about the criteria for awarding cancer center support grants (CCSG):

- There should be an existing base of high-quality, established programs in laboratory and/or clinical research, with peer-reviewed support from sources other than NCI.
- The center should have a qualified director with adequate authority. He should serve the center on a full-time basis, although he might also

have a concurrent academic commitment to an institution whose major activities are related and committed to the center.

So that the NCI can maintain maximum flexibility in its budget formulation, the Board opposed the identification of specific line items in the budget. It agreed to send this resolution to the Congress, noting that individual members could also contact their Congressmen as individual citizens if they wished.

November

To facilitate interchange between the NCAB and the Boards of Scientific Counselors (BSC) of the various NCI divisions, and to help the NCAB monitor programs supported by contracts and recommend policy to the NCI Director, the Board:

- Invited each of the BSC chairmen to attend all meetings of the Board and its subcommittees and to report on the year's activities annually at the November NCAB meeting.
- Asked the BSC chairmen to forward copies of their minutes and those of their subcommittees to Board members with clear delineations of BSC policy recommendations.

February

The Board agreed to use a combination of raw, rather than normalized, priority scores, plus the judgment of NCI program directors, in deciding which grants should be awarded.

It also approved the Subcommittee on Centers and Construction report which included the draft of revised guidelines for core grants, drawn up by the Division of Resources, Centers and Community Activities' (DRCCA) Board of Scientific Counselors.

May

The Board endorsed and supported the Organ Site Program, and requested that its budget be returned to its pre-rescission level. Also, the Board proposed that an in-depth review of the four existing projects be performed by an independent group with an eye to adding a fifth program.

The Board agreed to prioritize budget items, by mail, and to meet three times a year for discussion of the budget during the various stages of preparation. These meetings will coincide with the Board meetings.

The Board made plans to hear representatives from the American Association of Cancer Institutes (AACI) and the Association of Community Cancer Centers (ACCC) discuss the centers program, and discussed the possibility of holding regional meetings--a proposal to be discussed at the August meeting of the agenda and activities subcommittee. They also agreed to examine the issue of a ceiling for funds to a single investigator.

II. NCI REORGANIZATION AND PERSONNEL CHANGES

With approval of the NCI reorganization by the DHHS Secretary in June 1980, the NCI staff was able to proceed with all program and branch level changes begun by former Director Arthur Upton in May 1978. The sixth and last set of changes was issued by Dr. DeVita in July 1980.

At the November meeting, NCI staff reviewed the programs of the new Division of Resources, Centers and Community Activities (DRCCA). Dr. William Terry, Acting DRCCA Director, emphasized that the structure of the division has changed since it was approved by the Secretary and that it was being presented to the Board at this early, flexible stage so Board members may make suggestions. This division was created to bring the cancer centers and community outreach programs together and to give NCI a focal point for applied efforts in cancer prevention. It will incorporate programs of the former

Division of Cancer Control and Rehabilitation as well as many of those formerly in the Division of Cancer Research Resources and Centers. In addition, staff proposed establishing a Screening Branch and Chemoprevention Branch and transferring the Smoking, Cancer and Health, and the Diet, Nutrition and Cancer programs from the Office of the Director to the new division.

The division is now divided into three major programs: Education, Centers and Community Oncology, and Prevention (see Appendix for an organization chart).

Program directors and branch chiefs of DRCCA reviewed the history, status, future plans, and budget of their areas and pointed out their problems and needs, which in most cases resulted from inadequate funding, staff, and space. In addition, representatives from each of the NCI divisions described the portions of their programs dealing with smoking, diet and nutrition. Board discussion following these presentations dealt primarily with ways to avoid duplication of effort, ways to cut costs, and the question of continuing support of certain programs.

Along with the reorganization of NCI came some important staff changes: President Carter announced the appointment of Dr. Vincent T. DeVita, Jr., in July 1980, as Director of NCI. Dr. DeVita had served as Acting Director since the resignation of Dr. Arthur Upton in December 1979.

During this year, six search committees were formed to identify highly qualified people to fill the various vacant executive positions at NCI. These include executive officer, deputy director and directors for four of the Institute's five divisions. By February Dr. DeVita had interviewed candidates for all the jobs. Only his selection for executive officer was approved by DHHS before the administration changed in January 1981 and a hiring freeze was put into effect.

Throughout the year, the number of unfilled positions was a great concern to NCI staff. At the end of FY 1980, there were only 1,840 positions, 140 less than at the beginning of the fiscal year, due in large part to a hiring freeze. Such a situation has created difficulties at a time when new programs are beiny initiated and established ones are being reorganized; these include the Biological Response Modifiers, Diet and Nutrition, Smoking and Health, and Chemoprevention programs. In addition, pressure is being placed on NCI to curtail some of the work being done by contract in favor of having it done intramurally. The new Executive Officer is planning to review all NCI positions to consider how they might be reallocated to support the new programs.

At the October Board meeting, Dr. DeVita announced the following staff changes: Dr. Thomas King, Director of the Division of Extramural Activities (DEA) and executive secretary of the Board, left NCI to become Director of the Kennedy Institute of Ethics at Georgetown University. Dr. William Walter was named Acting Director and executive secretary of the Board. Dr. Gregory T. O'Conor, who was Director of the Division of Cancer Cause and Prevention (DCCP), resumed his former position as Associate Director for International Affairs; and Dr. Richard Adamson became Acting Director, DCCP.

Dr. John Bailar, resigned as Editor in Chief of the Journal of the National Cancer Institute; Dr. John Ziegler replaced him. Dr. Bruce Chabner was named the new Associate Director of the Clinical Oncology Program and Deputy Clinical Director of the Division of Cancer Treatment (DCT). Dr. Robert Oldham came from Vanderbilt University to direct the new Biological Response Modifiers Program, which is based at the Frederick Cancer Research Facility.

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Dr. Dennis Cain was appointed Chief of the Grants Review Branch, Division of Extramural Activities (DEA). Mr. Calvin Baldwin resigned as Executive Officer of NCI to assume the position of NIH Associate Director for Administration. Dr. DeVita announced the appointment of Mr. Philip Amoruso as NCI Executive Officer and the appointment of Ms. Barbara Harris as legislative analyst for the Institute in January.

An external EEO Advisory Committee now oversees the functions of the NCI personnel system to ensure balanced treatment of women and minorities in the program. NCI's Summer EEO Program was quite successful; 277 positions were filled by summer employees, 40 percent of them by women and 20 percent of them by other minorities.

III. NCI BUDGET

Reports from Dr. DeVita and from the NCAB Subcommittee on Planning and Budget kept the Board up to date on the complexities of and limitations imposed by the NCI budget. At the May 1980 meeting, Dr. Frederick Seitz, reported that his subcommittee had met with Dr. DeVita to review the NCI by-pass budget for 1982. The figures were based on the FY 1980 and 1981 levels contained in the original 1981 budget sent to the Congress, and the impact of a possible recession or amended 1981 budget had not been included. In general, the FY 1982 by-pass budget figures reflected a 12 percent rate of inflation and a 5 percent growth in the program. Total funds and positions were:

FY	Funds	Positions
1980	$1,000,802,000	2,059
1981	$1,007,800,000	2,066
1982	$1,192,000,000	2,239

Various aspects of the FY 1982 budget were summarized and compared to those of other budget years, including extramural funding (grants, contracts, interagency agreements), research and research project grants (R01, R23, P01), and funds for the National Toxicology Program, construction, and low level radiation. Budget tables were reviewed in a variety of formats including rescission, amended budget, thrust, research program, mechanism, and NCI division.

Dr. DeVita noted that the NCI has achieved, and exceeded the 1974 NCAB goal to increase investigator-initiated research by 1 percent per year for 3 years. At the conclusion of the budget reviews, the subcommittee passed a motion dealing with flexibility in budget formulation (Section I).

At the October meeting, Dr. DeVita reviewed the status of the 1980 and 1981 budgets submitted by President Carter and spoke briefly on the proposed 1982 budget. Amounts were:

1980	Original 1981 President's Budget	1981 Amended President's Budget	1981 House Allowance (Continuing Resolution)	1982 NCI By-pass Budget
$999,869,000	$1,007,800,000	$965,105,000	$1,001,330,000	$1,192,000,000

When President Carter submitted his amended budget for 1981, NCI was faced with a rescission of about $17 million (in FY 1980). This rescission budget was not approved by the Congress, and NCI staff redistributed those funds identified for rescission among various NCI programs. Board members received a chart showing a breakdown of these funds.

Dr. Donald Fredrickson, NIH Director, also reported briefly on the 1982 budget. He explained that NCI is receiving a proportionately smaller budget increase than the other Institutes because of the tremendous competition for dollars. He also urged the Board to tell congressional representatives about the need for biohazard containment and animal facilities for the grantees throughout the Nation.

In his budget update in November, Dr. DeVita explained that NCI had committed the entire $1 billion for 1980 and was expecting the markup from the Office of Management and Budget (OMB) for 1982. In 1981, NCI was operating under a continuing resolution due to expire December 15, which he expected to be extended until the following spring; the funding level was $1,001,330,000. Dr. DeVita explained the restraints that NCI is forced to impose on the fundings of grants, especially R01's, P01's, and cancer center core grants. He asked the Board for suggestions on alternate ways to distribute funds in this tight budget situation.

In February 1981, Mr. Louis Carrese, Associate Director for Program Planning and Analysis, presented the subcommittee's report for the Subcommittee chairman, Dr. Frederick Seitz. He noted that the FY 1981 budget had passed through five different versions and appears as $996,347,000 in the 1981 column of the 1982 congressional budget submitted by President Carter. The FY 1982 amount is $1,041,761,000.

The NCI share of the total NIH budget has been decreasing every year for the past several years. In addition NIH is tapping the NCI budget for several special projects. The NCI component of the National Toxicology Program will be transferred to the National Institute of Environmental Health Sciences by the end of 1981, along with $45.6 million plus funds for managing the program. NCI was requested to contribute $413,000 toward the study of the health problems experienced by the residents of Love Canal, while the share from all of NIH is $950,000. In light of the continually shrinking budgets, the Board suggested NCI consider not funding some of those research projects given assignments to two institutes. However, in the end NCI was not required to provide any funds.

Mr. Carrese reviewed the 1982 budget by research programs, comparing 1982 with 1981 dollar amounts. He also noted that NIH had set a firm target of 5,000 R01 and P01 competing research grants that NIH will fund, and he described the

hardships that this brings to bear on various programs. NCI prefers to be limited to a certain percentage increase rather than a fixed number of research grants. In the face of budget restrictions, the subcommittee recommended that NCI consider converting P01's, which are large research projects, to R01's.

IV. NATIONAL CANCER PROGRAM REAUTHORIZATION

Authorization for the National Cancer Program expired on September 30, 1980. Throughout the year, Dr. DeVita kept the Board up to date on the status of the reauthorization legislation.

The two bills under consideration were the Health Research Act of 1980 (H.R. 7036), sponsored by Congressman Henry Waxman, which passed the House on August 28, 1980, and the companion Health Sciences Promotion Act of 1980 (S. 988), sponsored by Senator Edward Kennedy, which passed the Senate.

The Waxman bill contained several provisions whose merits raised great concern to NCI and divided opinion on the Board. One was the requirement for the NCAB to review all research contracts costing more than $500,000 during the contracting period. Another was a line item for cancer centers of about $100 million. The bill also restricted use of the 301 by-pass authority, which gives NCI the authority to proceed with business without further authorization levels. The Waxman bill authorized the National Cancer Program at levels of $1.24 billion for 1981, $1.42 billion for 1982, and $1.6 billion for 1983.

The Kennedy bill made relatively minor changes in the National Cancer Act. It left the 301 authority intact, set no time or dollar limits, and provided for creation of the President's Council on Biomedical Research.

Since the House and Senate could not resolve their differences before the new Congress convened in 1981, they passed the Health Programs Extension Act of 1980 (P.L. 96-538), which was signed by the President on December 17, 1980. This Act extends the National Cancer Program through FY 1983.

V. NCAB'S RELATIONSHIP WITH THE DIVISIONAL BOARDS OF SCIENTIFIC COUNSELORS

At the Board's request, Dr. DeVita met with the Board of Scientific Counselors (BSC) of each division to discuss ways in which the NCAB could become more involved in the concept review of contracts, the following steps were taken to encourage the NCAB's involvement:

- Board members now receive minutes of the BSC meetings in which decisions of concept review have been highlighted.
- Board members have a standing invitation to attend meetings of the BSC.
- BSC chairmen will report on the activities of each division at the November program review meeting of the NCAB.
- BSC chairmen have a standing invitation to attend all meetings of the NCAB and its subcommittees.

These actions were prompted by legislation for reauthorization of the National Cancer Act, pending at the time; it required the NCAB to assume greater responsibility for the contract review, now handled primarily by the division BSC. It was also motivated by the establishment of a BSC for the new DRCCA, now responsible for reviewing contracts for the Organ Site and Cancer Centers programs. These programs are of great interest and concern to the NCAB.

This newest Board of Scientific Counselors, under the chairmanship of Dr. Stephen Carter, collaborated with the NCAB on the revision of guidelines for core support of cancer centers. They drafted a set of revised guidelines--based on suggestions made by the NCAB, NCI staff, cancer center directors, and other scientists and administrators in the field of cancer--and brought them to the NCAB for further recommendations and final approval.

Other actions by the BSC that are of interest to the Board include:

- A report summarizing a 3-year review of the Clinical Trials Program by the BSC for the Division of Cancer Treatment (DCT) that suggests the successful operation of this program has reduced cancer mortality nationwide.
- Creation of a new mechanism of Regional Cooperative Groups to parallel the current Cooperative Group Program of the DCT.
- Establishment of a DRCCA BSC subcommittee to make recommendations on the establishment of a chemoprevention program.

VI. REVIEW OF NCI CONTRACTS AND GRANTS

In October, Dr. DeVita presented the first of a series of three briefings on NCI contract activities. Dr. DeVita discussed the history of the contract in funding biomedical research and contrasted the difference between a contract and a grant. NCI was the first Institute to use the contract mechanism in 1956 to support its anticancer drug development program. Some of the problems the NCI faces in allocation of resources, the differences between basic and applied research, and a continuum of the funding mechanism as it relates to government involvement were all discussed.

Dr. DeVita explained the dual review process that provides overview for all NCI contracts. They are reviewed at the concept level by the appropriate divisional Board of Scientific Counselors and at the merit level by another review group, set up in a fashion similar to the peer review group used for grants. Concept review is done before a request for proposal (RFP) is issued and each time a contract is recompeted. Because the Boards of Scientific Counselors have responsibility for the total review of particular programs, including budget, they are in a good position to make decisions about the

appropriateness of a new contract. Each board reviews all the contract proposals and recompetitions for its division.

In February, Dr. DeVita highlighted changes in contracts from 1956 and detailed current contract review procedures at the pre-award, award and post-award stages. He asked the Board to consider these changes to solve some of the problems in the contract mechanism.

- Transfer of responsibility for merit review of contracts from the various divisions to the Division for Extramural Activities.
- Charter committees to review resource contracts separate from the BSC review of research contracts.
- Have the NCAB act as a Board of Scientific Counselors for the Office of the Director (OD). They would review OD programs and be responsible for concept review of OD contracts. The Board acted in this capacity by reviewing a proposal to study populations in Utah exposed to radioactive fallout between 1950 and 1962.

At the last of the series in May, Dr. DeVita contrasted the grant with the contract; the contract being a procurement and the grant an assistance mechanism. In the past, he felt NCI staff handled contracts as if they were grants and this led to various deficiencies detailed in the Inspector General's report of 1978 and the post-audit report of 1980. Dr. DeVita described the various steps staff have taken to correct the day-to-day business management of contracts. These changes affect primarily the project officers and contract officers and include correcting staff shortages, providing more extensive training and establishing a system of overview. At the May meeting, Dr. DeVita announced that all business functions related to both grants and contracts are being consolidated in the NCI executive office.

VII. FREDERICK CANCER RESEARCH FACILITY

This year the Board reviewed the total operation of the Frederick Cancer Research Facility (FCRF), now managed under contract by Litton Bionetics. This contract expires in September 1982 and both the Board and NCI staff were preparing for the recompetition.

Begun in 1972 as a government-owned/contractor-operated (GO/CO) facility, the FCRF is staffed primarily by Litton Bionetics personnel with a few NCI intramural scientists and administrators. NIH and NCI have agreed to gradually transform the facility from a contractor-operated to a Federal-operated facility, in part to help alleviate space problems at the main NIH campus. The following options on management of the FCRF were presented to the Board:

- Terminate the GO/CO contract.
- Continue the single contractor operation with gradual phase-out of all contractor responsibilities.
- Continue the single contractor until phase-out of all contractor program and management responsibilities; retain support contract.
- Continue as GO/CO with multiple contractors.

On May 20, 1980, Board members site visited the Frederick Cancer Research Facility. Dr. Michael Hanna, Director of the FCRF, and Dr. William Terry discussed the history of the facility and the development and management of the NCI contract with Litton Bionetics. Board members then toured the laboratories involved in the study of cancer biology, cancer metastasis and treatment, carcinogenesis, biological markers, and environmental control and research. They also heard reports by NCI division directors on the various programs at the FCRF.

To evaluate the options available for operating the FCRF, Dr. Pitot appointed an ad hoc FCRF subcommittee: Mr. Samuels, Chairman; Mr. Schrier,

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To evaluate the options available for operating the FCRF, Dr. Pitot appointed an ad hoc FCRF subcommittee: Mr. Samuels, Chairman; Mr. Schrier,

Dr. Amos, and Dr. Rowley. In October, Mr. Samuels reported that the subcommittee had no strong feelings about any one of the options, and that it was very pleased with FCRF management and the high quality of its science. They recommended that a permanent Board subcommittee supplemented by NCI management staff be formed to oversee the Frederick contract since the skills for management analysis do not exist on the Board.

NCI had moved some NCI laboratories from Bethesda to Frederick. Staff recommended to the Board subcommittee that the FCRF contract be recompeted as a 5-year contract at a 20 percent reduction and in two parts--one for research and one for resources and services. Dr. DeVita will appoint a staff member to oversee the contract and to work to improve the relationship between NCI staff and the contractors at Frederick. Although the contract will be smaller, Dr. DeVita expects that the high quality of research will be preserved.

A major program--Biological Response Modifiers Program under the direction of Dr. Robert Oldham--is already operating at the FCRF. In October, Dr. Saul Schepartz, Acting Director, Division of Cancer Treatment (DCT), described the history and present status of the Biological Response Modifiers Program. In 1978 the DCT Board of Scientific Counselors appointed Dr. Henry Mihich to chair a subcommittee to review the state of the art and develop a program plan. The committee held several workshops and in 1979 presented a plan to implement the program. It was agreed, for an initial project, to provide interferon for clinical trials. Proposals were solicited for the production of several types of the agent. Request For Proposals (RFP) were later issued for contracts to get the program started in 1980. During this year, about $4 million was spent for the purchase of interferon for clinical trials and a number of programs were established to evaluate biological response modifiers in Phase I and II clinical studies.

Now, a large portion of the fermentation facility at the Frederick Cancer Research Facility is devoted to production of biological response modifiers, especially interferon. In addition, a clinical program is being established at a nearby hospital where Dr. Oldham will carry out clinical studies.

Dr. John Macdonald, Associate Director for Cancer Therapy Evaluation, DCT, reviewed the discovery and development of interferon. He described the various types of interferon, and summarized clinical trials designed to study the anti-cancer effects of this agent. The DCT-supported studies will seek to determine the optimum dose and schedule for interferon, the diseases most responsive to it, and the best times to administer it.

VIII. ENVIRONMENTAL CARCINOGENESIS AND PREVENTION

Developments in environmental carcinogenesis and cancer prevention continued to be of great interest to the Board this year. Of major consideration was the transfer of the NCI component of the National Toxicology Program (NTP) to the National Institute of Environmental Health Sciences (NIEHS). The subcommittee endorsed the transfer of the NCI Carcinogenesis Testing Program, along with $49.987 million and about 95 positions, to the NIEHS, and the Board concurred (Section XIII, item 2). The transfer will eliminate certain operational and administrative problems, reduce the difficulty of recruiting professional staff, and simplify the definition of fiscal budgets and program costs. NCI will continue to be involved in the testing activities through the NTP Executive Committee, the NTP Board of Scientific Counselors, and operational committees.

Dr. David P. Rall, Director of the NIEHS and of the NTP, explained the function of the NTP, established in November 1978 to coordinate the previously

diverse efforts at toxicological testing, test development, and test validation within the Public Health Service (PHS). Major NTP activities include the bioassay program of the NCI, the environmental mutagenesis testing program of the NIEHS, programs to develop methods more relevant to regulatory needs in the National Center for Toxicological Research, and the toxicology research program of the National Institute for Occupational Safety and Health (NIOSH) to delineate the hazards of workplace chemicals.

The NTP's primary advisory body is its Executive Committee, composed of representatives of research and regulatory agencies. Among them are the directors of the NIH, NCI, NIEHS, and NIOSH. Representing the regulatory agencies are the administrators of the Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), Consumner Product Safety Commission (CPSC), and Food and Drug Administration (FDA).

At the beginning of each fiscal year, the NTP will publish an annual plan that will list the chemicals to be tested, how they are to be tested, test development activities to be undertaken, and other research opportunities. The plan will also list all relevant toxicology research and testing going on within the PHS.

The NTP also has a Board of Scientific Counselors. This board is examining three important areas: the best way to select chemicals for testing; the mechanism for reviewing technical reports; and automatic data processing needs.

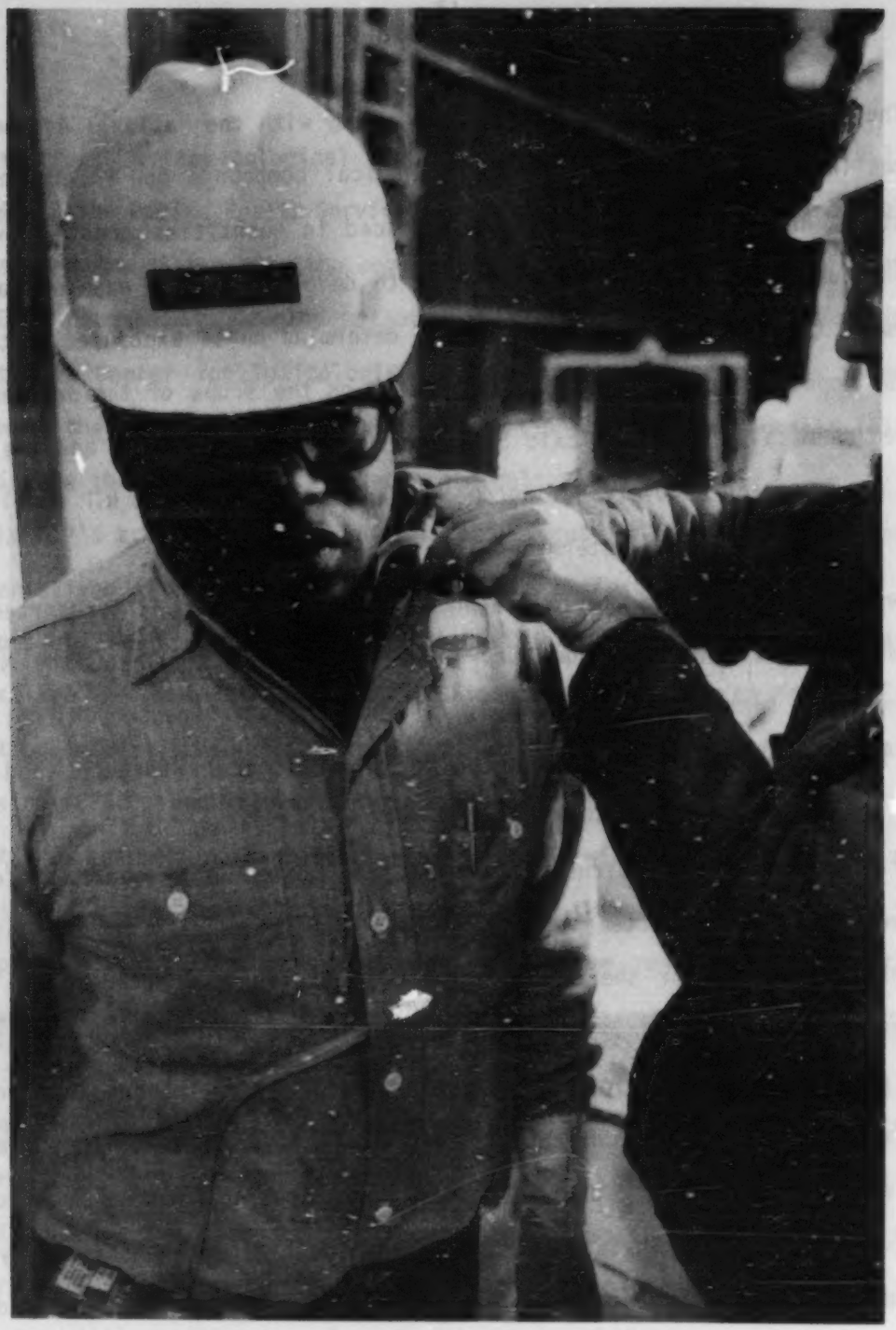
Dr. Rall described the various NTP activities to date. Protocols for standard toxicity studies have been broadened, capabilities to study 15 to 20 chemicals a year have been developed, an environmental mutagenicity test program in NIEHS is now functioning and is being integrated with NCI's short-term test development, and renal and neurobehavioral toxicology studies are being integrated into the general NIEHS testing program.

The NTP is initiating a "testing need" study with the National Academy of Sciences (NAS). There are about 50,000 chemical compounds now in commercial production, and about 25 of them are produced in quantities greater than a million pounds a year. The NAS will try to develop ways to examine random samples of these 50,000 chemicals, and to determine human exposures to them. NTP thus hopes to obtain baseline information on the scope of the problem of untested chemicals. As the Toxic Substances Control Act (TSCA) and the Resource Conservation Recovery Act become implemented, and as the NTP develops, future test needs will be determined.

Representatives from the four agencies participating in NTP reported on their activities. They included Dr. Richard Griesemer, Head of the NCI's Carcinogenesis Testing Program; Dr. J. A. Moore, Deputy Director, NIEHS; Dr. Ronald Hart, Director, National Center for Toxicological Research; and Dr. Anthony Robbins, Director, NIOSH.

Dr. Emmett Barkley, Director of the NIH Office of Research Safety, reported to the Subcommittee on Environmental Carcinogenesis on the latest draft of "Guidelines for the Laboratory Use of Chemicals Carcinogens." (He had presented the first draft to the subcommittee in 1979.) The guidelines are to provide safeguards for workers using chemical carcinogens in laboratories within DHHS. Areas covered in the guidelines include health surveillance, employee education, and laboratory practices/engineering controls.

Dr. John Holbrook, Assistant Professor of Medicine at the University of Utah Medical School, reviewed the status of the changing cigarette, and discussed populations who are now smoking. He spoke to the Board in connection with NCI's Smoking, Cancer and Health Program, which is to be included in the new DRCCA. He summarized the Surgeon General's reports of 1964, 1979,



Educating workers on ways to minimize exposure to carcinogens using measures such as protective clothing and "sniffing" devices is part of applied prevention efforts.

and 1980, which discuss smoking and disease, the alarming increase in lung cancer incidence in women, and the effects of passive smoking on nonsmokers. He also discussed a conference held in 1980 that dealt with the relative health risks associated with smoking cigarettes of various nicotine, tar, and carbon monoxide content; and the health risks of cigarettes that contain additives. The conference was held as a result of the 1978 Health Services and Centers Act.

In November, Dr. DeVita told the Board that Dr. Oddvar Nygaard and Dr. David Pistenma had completed a report on how to organize radiation research at NCI, especially low level radiation. NCAB members will soon receive the report and are invited to comment on it. The report is a result of departmentwide effort to examine radiation research and its potential dangers.

In February 1981, Dr. Nygaard described a contract proposal to assess leukemia and thyroid disease in the population exposed to radiation fallout from atomic tests conducted in Utah between 1950 and 1962. For the first time, Board members exercised their new responsibility to concept review those contracts emanating from the NCI Director's office. They approved the concept of a plan for a sole source contract at a cost of no more than $1 million over a period of 5 years, with the condition that no Federal employees participate in the review for scientific merit. This provision was made to avoid conflict of interest. The NCAB will review the proposal again if peer review is favorable.

IX. CANCER CENTERS

In February 1981, Board members received the revised guidelines for awarding NCI cancer center support (core) grants, almost 4 years after the first changes were proposed.

Core grants are designed to support the elements needed for planning, development, evaluation, administration, and maintenance of an active, unified cancer center. The grants include professional staff salaries, administrative costs, development projects, and shared resources, services, and equipment. Budgetary restrictions made it necessary to modify the guidelines to continue a broad-based cancer centers program; a major concern of the NCAB was the increasing amount of money being spent on investigator salaries.

The Board of Scientific Counselors of the DRCCA drew up the revised guidelines, incorporating policies proposed by the NCAB's Subcommittee on Centers and Construction, under the chairmanship of Dr. Maureen Henderson (Section I). A copy of the guidelines approved by the NCAB and the Board of Scientific Counselors of the DRCCA is in Appendix 2.

The NCAB submitted to the DRCCA Board of Scientific Counselors their views on several major issues to be considered in revising the guidelines:

- There should be flexibility in the issue of multiple core grants awarded to one institution; the BSC should identify circumstances in which multiple core grants are permissible.
- Supplemental applications should not be acceptable.
- A ceiling should be placed on staff investigator salary support.

X. ADDITIONAL REPORTS AND TOPICS OF INTEREST

Decade of Discovery.

December 23, 1981 marks the 10th anniversary of the National Cancer Program, which was initiated by the U.S. Congress during the administration of Richard Nixon. The National Cancer Advisory Board will publish a report, Decade of Discovery: Advances in Cancer Research 1971-1981, to commemorate this anniversary. This year the Board reviewed the report and followed its

development closely. It discusses in a popular fashion the progress that has been made towards our ultimate control of this disease in areas of treatment, prevention and basic research. The report will be presented to the Secretary, the President, and the Congress in FY 1982.

International Activities. In 1979, the NCI signed a memorandum of understanding with the Cancer Institute, Beijing, People's Republic of China for cooperative research in cancer science and technology. Dr. Gregory O'Conor, Associate Director for International Affairs, reviewed the functions of his office and described the activities of the International Cancer Research Data Bank Program. He reported that during 1979, 44 grants totaling $2.4 million, and 78 contracts totaling $8.8 million, were awarded to scientists in 21 different countries.

Cancer Treatment. Dr. DeVita described the Laetrile studies in progress throughout most of FY 1981, and at the May meeting reported the phase II study in 178 patients showed the substance to have no anticancer effect.

An Investigational New Drug (IND) application for the use of leukocyte interferon in clinical trials was approved. Genetically engineered interferon will also be tested. About 17 other new drugs--products of NCI's Drug Development Program--are almost ready for animal testing, but rising costs may slow this testing program.

Dr. DeVita also spoke about problems in technology transfer. He noted that 200,000 patients are receiving chemotherapy and 46,000 can be expected to obtain maximum benefit. He said this issue must be faced, and that health care professionals must be trained to apply the best technology. At the same time, more patients should be entered into studies to improve our methods of cancer treatment.

Community Hospital Oncology Program (CHOP). NCI has received criticism for funding such a small number of hospitals under this program. Careful review of the applicants, though, showed that only 23 were eligible for funding; they have been awarded $13.1 million. Despite the decrease in the budget for cancer control, this program received high priority for funding.

Clinical Manpower Needs. At the February meeting, Dr. Margaret Edwards, Chief of the Clinical Manpower Branch, DRCCA, described a study performed to determine the need for various types of cancer-oriented specialists by 1985, including medical oncologists, pediatric hematologists, gynecologists, and surgeons. The study, done by Geomet, Inc., under contract to NCI, was begun in 1975. A similar study, supported by a private organization, determined the needs by 1980. Dr. Edwards pointed out the disagreement in the results of the two studies and explained the difficulties in assessing manpower needs. Her report was made to answer questions posed by Board members at the previous meeting, when she described the activities of the Clinical Manpower Branch.

Testicular Cancer. Dr. Seitz expressed concern that the early symptoms of testicular cancer are not widely publicized. Dr. DeVita said that this form of cancer is treatable but that its incidence is rising, and said that testicular self-examination should be emphasized. Mr. Van Nevel, Associate Director of the Office of Cancer Communications, indicated that his staff is gathering material to deal with this problem.

Cancer Information and News Coverage. A discussion at the October meeting centered briefly on distribution of newspaper clippings pertaining to cancer and the obeservations made in the press that the incidence of cancer has increased to "epidemic" levels. Dr. DeVita pointed out that most of our present data come from the Third National Cancer Survey and the Surveillance

Epidemiology and End Results (SEER) Program data base. While these data are now somewhat "soft," it is hoped that they will soon become firmer.

Dr. Amos had suggested in October that an hour at each meeting be devoted to matters of the National Cancer Program of public concern. In February, Dr. DeVita indicated that press coverage had been favorable to the NCP over the past few months and reviewed some of the cancer-related items that had appeared in the media.

Conference on Cancer and Aging. In September, Dr. DeVita and members of the NCAB attended a conference co-sponsored by the National Retirement Research Foundation, Bankers Life and Casualty Company, the National Institute on Aging, and the NCI, at which 40 scientists from seven countries presented their work. Workshops are being planned around the world to expand on particular areas highlighted during the conference. The proceedings will be published as a monograph of the Journal of the National Cancer Institute and as Proceedings of the House Select Committee on Aging.

Mortality Followup Study. NCI was asked to contribute funds to a followup study of the National Death Index. Dr. Robert Miller, Chief of the NCI Clinical Epidemiology Branch, described the establishment of the National Death Index and explained how helpful and inexpensive it would be for followup of subjects in epidemiological studies. Dr. Manning Feinlieb, of the National Heart, Lung, and Blood Institute, described a proposed study for long-term followup of diseases among individuals who completed the long form in the 1980 U.S. census. He said that NHLBI will first conduct a pilot study. If the results are acceptable, NCI will be asked to contribute to a full-scale NIH-wide study. Board members decided to postpone a recommendation on whether to fund the Index until the results of the pilot study are available.

Debarment Regulations. Dr. Fredrickson reported that DHHS had developed debarment regulations to deal with the problem of those who misuse Government funds provided for biomedical research or those who violate the code of ethics in medicine. Mr. Richard Riseberg, the General Counsel's representative at NIH, explained the regulations in detail. Dr. Fredrickson said the NIH will look to the Advisory Boards and Councils of the various Institutes for guidance in deciding about continuing support of individuals while debarment proceedings are in progress. He pointed out that debarment is rare and that these regulations protect the individual as well as the government.

XI. NCAB MEMBERSHIP AND ACTIVITIES.

Terms of these Board members expired in 1980: Dr. William D. Baker, Dr. G. Denman Hammond, Dr. Joseph H. Ogura, Dr. William W. Shingleton, and Mrs. Albert D. Lasker.

The President reappointed Dr. William G. Powers to serve until 1986, and Dr. Henry Pitot to serve as board chairman until 1982. He also appointed the following new members, whose terms expire in 1986: Dr. Robert C. Hickey, Professor of Surgery, M. D. Anderson Hospital; Dr. Joseph Gale Katterhagen, Director of Oncology, Tacoma General Hospital; Mrs. Rose Kushner, writer, Kensington, Maryland; Ms. Ann Landers, Field Newspaper Syndicate, Chicago, Illinois; and Dr. LaSalle D. Leffall, Professor and Chairman, Department of Surgery, Howard University.

New alternates to ex-officio members include Dr. Peter W. Preuss, Associate Executive Director, Health Sciences, replacing Dr. Joseph McLaughlin as alternate for Ms. Susan B. King; Dr. Hollis Boren, Assistant Chief Medical Director for Research and Development, Veteran's Administration, replacing Dr. Marguerite T. Hays as alternate for Dr. Donald L. Custis; and Dr. Gary

Flamm, Deputy Associate Commissioner for Science, Food and Drug Administration, replacing Dr. Joseph Rodricks as alternate for Dr. Jere Edwin Goyan. Mr. Richard S. Schweiker, the new Secretary for the Department of Health and Human Services, replaces the former Secretary, Mrs. Patricia R. Harris, as an ex-officio member. The new executive secretary of the Board is Dr. William A. Walter, Acting Director, NCI Division of Extramural Activities, replacing Dr. Thomas J. King.

The Board subcommittees continued to be active this year, reviewing programs and dealing with various cancer-related issues. The Subcommittee on National Organ Site Programs, under the chairmanship of Dr. William Powers, performed a systematic review of all four projects--Bladder, Large Bowel, Pancreas, and Prostate. The subcommittee concluded that the Organ Site Programs are effective and successful. They urged NCI to continue to support these programs, despite problems with funding; to phase them out now would be premature, they said, and would likely result in a decrease in the number of investigators studying these diseases.

The ad hoc Subcommittee on Cancer in Minorities examined the problems of Blacks and Hispanics. Dr. LaSalle Leffall, chairman of the subcommittee, reported that, with the exception of skin and breast cancer, the incidence in Blacks is greater for every major form of cancer. He also reviewed the 1979 American Cancer Society (ACS) conference on problems of cancer in Blacks. Dr. Leffall presented the subcommittee's recommendations, which included close cooperation with the activities of the ACS, providing a reliable data base and additional information, training of minority medical personnel and epidemiologists, a program to bring minorities to the cancer centers, and additional statistical studies.

Other subcommittees reported to the Board during the year; their reports are incorporated into other sections of this report. They include the Subcommittees on Environmental Carcinogenesis, Centers and Construction, NCAB Activities and Agenda, and Budget and Planning; and the ad hoc Subcommittees on Nutrition and on the Frederick Cancer Research Facility.

In February 1981, subcommittee chairmen reviewed the historical perspective of their groups, explaining their functions and accomplishments. Dr. Henderson presented the report on the ad hoc Subcommittee on Nutrition; Dr. Powers, the Subcommittee on the National Organ Site Program; Dr. Pitot and Dr. Wogan, Environmental Carcinogenesis; Dr. Amos, Activities and Agenda; and Dr. Walter, for Dr. Henderson, Centers and Construction.

The Nutrition Subcommittee is relatively new. Its members, Drs. Henderson, Ames, Wogan, Amos, and Pitot, have met twice and plan other meetings to obtain information from the NCI's Diet, Nutrition and Cancer Program, on the research and problems now existing in the field of nutrition.

The Subcommittee on Environmental Carcinogenesis has been inactive since the bioassay program was transferred to the NIEHS. The Subcommittee on Board Activities and Agenda is now responsible for assisting in the preparation of the NCAB Annual Report and will begin this with this report.

The Subcommittee on Centers and Construction did not help to formulate the 1976 guidelines for awarding core grants; however, they have been very active in the current revision of the guidelines, as explained earlier in this report. Subcommittee members feel they can play an important role in helping NCI to decide about current issues on cancer centers. They recognize the need to cooperate with the DRCCA Board of Scientific Counselors in many of these matters.

XII. PRESIDENT'S CANCER PANEL MEMBERSHIP AND ACTIVITIES

The President appointed Dr. Harold Amos as the newest member of the President's Cancer Panel for a term expiring in 1983. He joins Dr. Bernard Fisher (1982) and Dr. Joshua Lederberg, Chairman (1981).

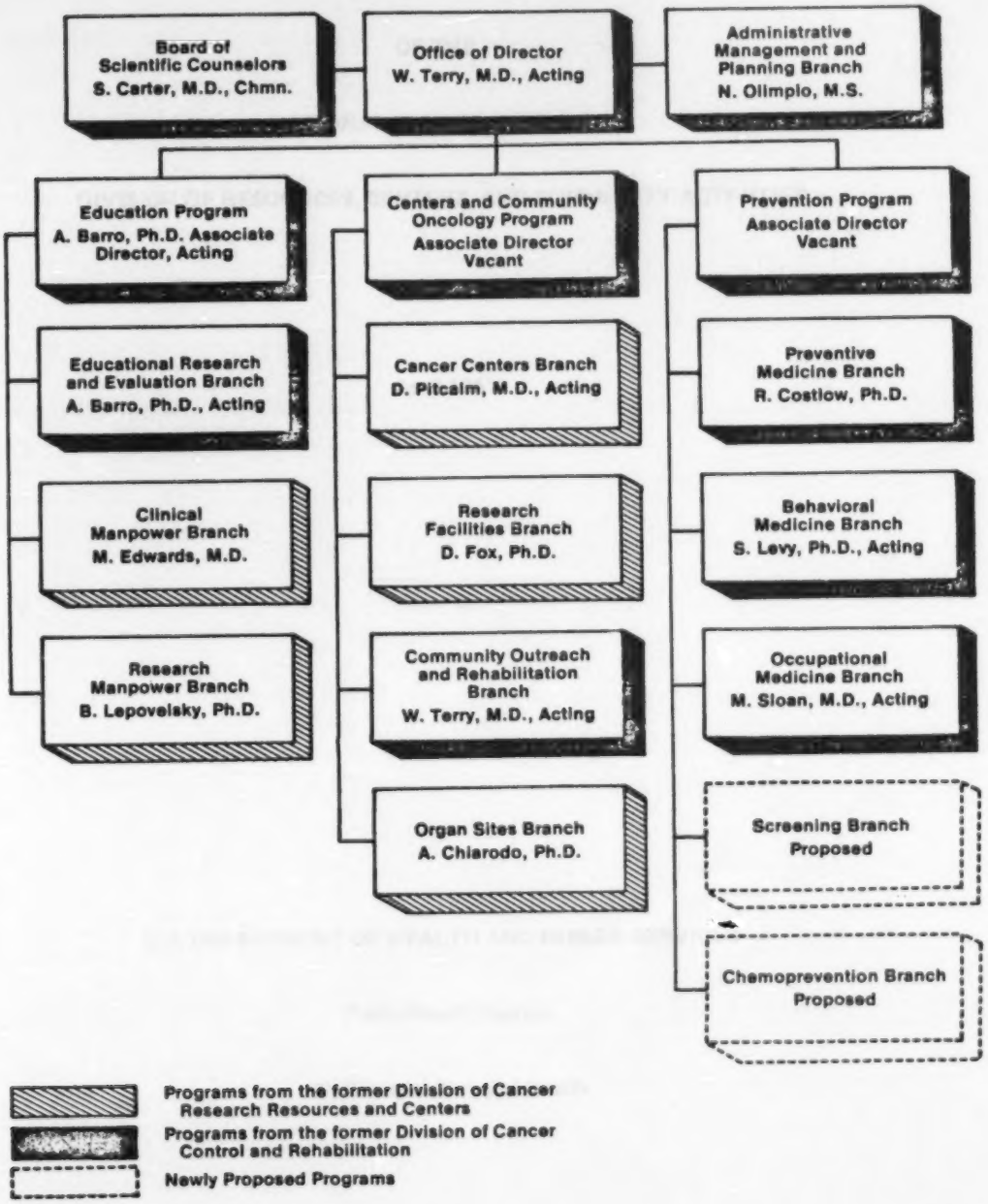
Dr. Lederberg, who began his term in 1980, described areas that might be explored to assist the Panel, the Board, and the country as a whole in understanding the dimensions of the problems related to cancer and the progress that has been achieved. He recommended careful examination of innovative approaches to the management of cancer prevention and therapy and the controversy over the rise in cancer incidence as it relates to a deteriorating environment. Dr. Lederberg suggested that this might be done by holding a number of public conferences. He asked Board members to try to reach a consensus on controversies that should be dealt with.

The Panel expressed its concern about the deterioration of morale of creative investigators brought about by the current system of awarding grants. It feels more weight should be given to the investigator's performance and creativity in awarding grants. Dr. Lederberg requested that Dr. DeVita designate a member of the NCI staff to investigate the options currently available in grants management and to prepare a report on this for review by the Panel and Board.

The Panel also initiated an evaluation of their role for the next 2 to 3 years in light of the changes that have taken place since the National Cancer Program began in 1971. They expressed the need, in this new phase, to re-evaluate the mission of NCI and restate the primary goals of the National Cancer Program. The Panel met with Dr. DeVita several times this year for a series of briefings on plans for program redirection and a reorganization of

NCI leadership. It is the Panel's intent to set new directions for themselves, with the help of information gleaned from NCI staff, the National Cancer Advisory Board, and members of the scientific community.

Appendix I
Division of Resources, Centers, and Community Activities
Proposed Organization



APPENDIX II

GUIDELINES FOR THE

CANCER CENTER SUPPORT GRANT

OF THE

NATIONAL CANCER INSTITUTE

DIVISION OF RESOURCES, CENTERS, AND COMMUNITY ACTIVITIES

April 1981

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

CONTENTS

		Page
1.	Introduction	1
2.	National Cancer Institute Support for Cancer Centers	1
3.	Purpose and General Provisions of a CCSG	2
4.	Eligibility for Submission of Applications	3
5.	Essential Characteristics of Cancer Centers	3
	5.1 Interdisciplinary Coordination	3
	5.2 Organizational Capability and Facilities	4
	5.3 Center Director with Adequate Authority	4
	5.4 Institutional Commitment	5
6.	Submission Requirements	6
	6.1 Letter of Intent	7
	6.2 Consultation with Cancer Centers Branch Staff	8
	6.3 Letter of Certification	8
7.	Limitation on the Amount That May Be Requested in a CCSG Application	8
8.	Project Period	9
9.	Allowable Budget Items	9
	9.1 Professional Personnel Salaries	10
	9.2 Developmental Funds	13
	9.3 Administration	14
	9.4 Planning and Evaluation	14
	9.5 Shared Resources and Services	15
	9.6 Hospitalization and Clinical Research Costs	16
	9.7 Alteration and Renovation	16
10.	Special Instructions for Preparing Cancer Center Support Grant Applications, New and Renewal	17
11.	Grant Review Procedures Applicable to a Cancer Center Support Grant	21
12.	Review Criteria	21
13.	Negotiation and Award	22
14.	Reporting Requirements (Annual Report)	22
15.	Publications	22

1. INTRODUCTION

Since the early 1960's, the National Cancer Institute (NCI) has conducted a Cancer Centers Program to provide grants for support of multidisciplinary programs in cancer research at educational and research institutions in the United States. Enactment of the National Cancer Act of 1971 gave further impetus to this effort through its provisions for strengthening existing centers and supporting the establishment of new ones.

Cancer centers have developed in a number of different organizational settings: Some are independent, free-standing institutional entities; others are under the auspices of universities, often involving several colleges; and still others are consortia or multi-institutional in nature. Although a cancer center needs a certain minimum number of research programs for a "critical mass," existing centers vary greatly in size and breadth of programs from rather small, specialized centers to large, complex comprehensive centers. They have developed from existing areas of strength at the parent institutions into coordinated multidisciplinary programs of several types: (1) Laboratory Cancer Research Centers (LCRC)--centers engaged only in laboratory research; (2) Clinical Cancer Research Centers (CCRC)--centers engaged only in clinical research; and (3) Cancer Research Centers (CRC)--centers engaged in both laboratory and clinical research.

In addition, a Cancer Research Center with a funded Cancer Center Support Grant (CCSG) may apply to the National Cancer Institute for recognition as a comprehensive cancer center. Such recognition may be granted by the Director of the National Cancer Institute if evaluation of the center demonstrates compliance with the Guidelines for Recognition of a Cancer Center as Comprehensive. These guidelines were established by the National Cancer Advisory Board, and may be obtained by writing to Chief, Cancer Centers Branch, National Cancer Institute, NIH. Note that recognition as comprehensive is not associated with receipt of additional CCSG grant funds, and that the degree to which a cancer center meets the guidelines for comprehensiveness is not a factor in the review or award of CCSG's.

2. NATIONAL CANCER INSTITUTE SUPPORT FOR CANCER CENTERS

NCI provides grant and/or contract support for cancer center activities in laboratory and clinical research, training, education, detection, cancer control, and facilities construction. Core support for the research activities of cancer centers is provided by the CCSG as described in these guidelines. Assistance in determining potential sources of support for these cancer center activities may be obtained from:

Chief, Cancer Centers Branch
Division of Resources, Centers, and
Community Activities
National Cancer Institute
National Institutes of Health
Blair Building, Room 714
Silver Spring, Maryland 20910

3. PURPOSE AND GENERAL PROVISIONS OF A CCSG

A major purpose of the Cancer Centers Program is to foster and support the development of multidisciplinary programs in laboratory and clinical cancer research. The major funding mechanism for this purpose is the Cancer Center Support Grant, also referred to as a "core" grant (coded as a P30 grant by NIH).

A CCSG is designed to support those activities that will consolidate and focus cancer-related research efforts in a single administrative and programmatic structure. Except in unusual circumstances, applications for additional separate CCSG's will not be accepted from groups, departments, or other units of institutions* with funded CCSG's. Increases in core support will be provided only through an existing funded center.

CCSG support is intended to contribute to stability and development of the center and to facilitate administrative and programmatic control of center activities. The CCSG provides funds for salaries of selected staff, for the operation of centralized shared resources and services, and for the administration of the center. In addition, the CCSG may provide developmental funding for (a) investigators who have not previously had funded grants and/or newly recruited investigators; (b) interim research support for investigators of the center; and (c) new shared resources. These developmental funds are limited in duration and amount (see Section 9.2). Support of all other cancer center functions must depend upon other Federal and non-Federal funding mechanisms, such as regular research grant projects, program project grants, cancer control grants, training grants, education grants, research contracts, state funds, institutional funds, and private donations.

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* In the case of a statewide university system or similar organization, "institution" is herein defined as a major unit of such a system rather than the system as a whole.

4. ELIGIBILITY FOR SUBMISSION OF APPLICATIONS

Non-profit institutions within the United States may apply for CCSG's.

Application institutions must have an adequate base of established programs of high quality in laboratory and/or clinical cancer research. The high quality of the programs should be evident from the fact that they have been awarded support through national peer reviewed competition, such as in the form of NCI grants and contracts.

In order to apply for a CCSG, an institution must have a "base"* of at least $750,000 direct costs in peer reviewed research and research training support. This requirement is not meant to imply that the center must "control" all of these supported programs.

5. ESSENTIAL CHARACTERISTICS OF CANCER CENTERS

While the existence of high quality research programs at a center is a requirement for application, a number of other factors are essential for an effective cancer research center. Before a new or renewal CCSG may be awarded, peer reviewers of the application must conclude that a center demonstrates a number of additional essential characteristics. The degree to which each of these characteristics can be documented will be a major determining factor in the peer reviewers' evaluation and ranking of the application.

5.1 Interdisciplinary Coordination

There must be research activity in a variety of disciplines and there must be evidence of a high degree of interdisciplinary coordination, interaction, and cooperation among center members. Scientists or clinicians, conducting independent research with limited or non-existent interdisciplinary interactions, cannot be considered to be functioning collectively as a center. Such individuals are supported more suitably by other mechanisms, such as

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* Defined as including NCI awards with identifying numbers with the following prefixes: Research Grants, R01, R10, R26, R23, P01; Training, K04, T32, F32; Research Contracts, N01-CG, N01-CP, and N01-CM; and NCI Cancer Control Grants (R18) with a major research component. Contracts that support primarily the production of materials in support of research (e.g., virus production, animal production) will not be included. The base may also include research grants and awards from the American Cancer Society and 25 percent of the research grant and research training support from other NIH Institutes and the National Science Foundation. Contracts from sources other than NCI may not be included.

individual research grants (R01). A center's core support should facilitate creative interactive research activities such that "the whole is greater than the sum of its parts," and should increase efficiency by providing support for shared equipment and centralized multi-user facilities.

Examples of interdisciplinary coordination and cooperation within a cancer center include, but are not limited to: (a) collaborative, interdisciplinary laboratory research efforts; (b) multidisciplinary clinical research or clinical trials; (c) collaboration among laboratory, clinical, and epidemiological investigators; (d) publications resulting from such efforts; (e) significant sharing of facilities and equipment; and (f) seminars involving all center members.

5.2 Organizational Capability and Facilities

The center must have appropriate and adequate organization and facilities for the conduct and evaluation of center activities. The facilities and organizational arrangements should facilitate collaboration among constituent programs.

5.3 Center Director with Adequate Authority

The center must have a qualified director with adequate authority. The center director must be serving on a full-time or on a significant part-time basis and should have the authorities listed below. It is realized that a director of a consortium center cannot have direct authority over personnel, space, or equipment in the member institutions of the consortium. The consortium director, on the other hand, should have adequate authority over the "headquarters" operation of the consortium.

The authorities of a center director should include:

- Control of appointments or, at a minimum, joint control (with department chairmen) of appointments within the center; these appointments should be administratively indistinguishable from department appointments.

- Full control of center space and equipment, or control equivalent to that of a department chairman at that institution.

- If the center has a clinical component, the center director or his designee must have control of identifiable clinical research facilities.

5.4 Institutional Commitment

There must be an adequate commitment of the parent institution or institutions to the cancer center. The center should be recognized as a major element within the organizational structure. Institutional commitment may be manifested by various combinations of personnel, facilities, and financial obligations and commitments.

It should be emphasized that the application and site visit presentations must provide evidence for fulfillment of these characteristics and that this will be a major determining factor in the review and approval of applications for cancer center support grants.

6. SUBMISSION REQUIREMENTS

Applications for a CCSG must meet the submission requirements established by NIH and NCI. No application will be accepted unless a Letter of Certification from the Cancer Centers Branch, NCI, is included as part of the application (see Section 6.3). The receipt dates and review schedule are as follows:

Letter of Intent Due	Aug. 1	Dec. 1	April 1
Application Receipt Date	Feb. 1	June 1	Oct. 1
Review Committee Meeting	June/July	Oct./Nov.	Feb./March
NCAB Meeting	Sept./Oct.	Jan./Feb.	May
Earliest Possible Beginning Date	Dec. 1	April 1	Aug. 1

In order to be reviewed promptly, applications must be complete when submitted. Late submission of material designed to either complete or expand the application may result in deferral of the application. If applicants discover omissions or errors, they should contact the Grants Review Branch, NCI. The address is:

Grants Review Branch
National Cancer Institute
National Institutes of Health
Westwood Building
Bethesda, Maryland 20205

6.1 Letter of Intent

6.1.1 New Applications (Type 1)

The initial step in the application process is the submission of a Letter of Intent at least 6 months prior to the planned submission of a new CCSG application. The letter, no longer than 20 pages, should be directed to:

Chief, Cancer Centers Branch
Division of Resources, Centers, and
Community Activities
National Cancer Institute
National Institutes of Health
Blair Building, Room 714
Silver Spring, Maryland 20910

NCI staff will review the Letter of Intent and discuss its contents with the applicant to determine if the proposed center meets the minimum requirements described in these guidelines. NCI staff will discuss budget estimates and projections and advise the applicant concerning the preparation of a formal application.

For a new application, the Letter of Intent should summarize the present state of planning and development of the proposed center by providing the following information:

I. The type of center proposed (Laboratory Cancer Research Center; Clinical Cancer Research Center; or Cancer Research Center).

II. The center's objectives.

III. A brief summary of events leading to the current status of the cancer center.

IV. A description of the proposed activities, and specific indications of the ways in which the center will meet each of the essential characteristics of a cancer center (see Section 5). This information must be adequately documented to enable Cancer Centers Branch staff to advise concerning eligibility for a Cancer Center Support Grant.

V. A list of staff who are expected to participate in the center programs, including titles, tenure status, and areas of research interest.

VI. A list of current funded and/or pending grants and/or contracts, for the staff listed under Part V, above. For each grant or contract, please include:

A. Source of funds
B. Amount of funding (direct costs; if other, please indicate)
C. Identifying numbers
D. Whether funded or pending, and
E. Date of funding, initiation, and termination.

VII. Documentation of the source and allocation of state, local government, foundation, or institutional funds made available to the center and an indication of the authority the center director has over these funds.

VIII. A statement of the center director's authority relative to appointments to the center, center space and equipment, and, if pertinent, control over clinical research facilities.

IX. Charts showing the existing or proposed organizational structure of the center and its relationship to the applicant institution and, where applicable, to affiliated or collaborating institutions.

X. An estimated first-year budget for the CCSG and future annual projections for an additional 2 years.

6.1.2 Competing Renewal Applications (Type 2)

An applicant must submit a Letter of Notification of intent to submit a renewal application at least 6 months before submission of such a proposal. The letter should be sent to the Program Director, Cancer Centers Branch, NCI, responsible for the current grant. This letter should specify any major changes in personnel, program, or budget that have occurred since the last application and should contain an estimate of the funds to be requested by the renewal application.

6.1.3 Competing Supplemental Applications (Type 3)

Supplemental applications are discouraged and awards will be made only under very special circumstances. A Letter of Intent, which must be submitted 3 months before the application, should fully describe the justification for submission of a supplemental application.

6.2 Consultant with Cancer Centers Branch Staff

For new, competing renewal, or supplemental applications, Cancer Centers Branch staff will contact the applicant after receipt of the Letter of Intent and arrange for a meeting to discuss the application. This meeting is required unless the Cancer Centers Branch staff concludes it is unnecessary.

Following this consultation, an applicant may request written clarification of any issues or answers to questions relevant to the application from Cancer Centers Branch staff. The letters containing questions and answers will be available to site visitors and the Review Committee.

6.3 Letter of Certification

Following the above consultation(s), the Cancer Centers Branch will provide a letter certifying that the foregoing administrative steps have been accomplished. It should be made clear that the Cancer Centers Branch will not conduct a "peer review" before providing the certification. The provision of the letter will confirm that a Letter of Intent has been submitted, that the applicant institution meets the minimum requirement of $750,000 in the support base, and that consultation with the NCI staff has occurred (see Section 6.2). In the case of renewal applications, the letter will specify the maximum amounts that can be requested. This letter must be incorporated into the formal application. Applicants not including this certification will not be accepted.

7. Limitation on the Amount That May Be Requested in a CCSG Application

The maximum amount that may be requested for any one year is $5 million in direct costs.

Furthermore, NCI has established ceilings on the amounts that may be requested in renewal (Type 2) applications for CCSG's. Ceilings have been established both on the total direct costs and on staff investigator salaries. The latter is described in Section 9.1.3.

The ceilings on total direct costs for renewal requests are as follows.

For applications requesting 5 years of support, the average annual direct costs requested may not exceed an amount 50 percent higher than the current level (the direct costs committed or provided by the NCI for the 12 months prior to the requested beginning date of the renewal application). The average is to be computed on the basis of constant dollars with the first renewal year as the base. Projected increases for personnel, supplies, and other expenses may be requested in future years. An example for clarification is: If a grant has a current level of $1 million direct costs in the -06 year, a renewal application requesting 5 years must average no more than $1.5 million per year using the -07 year as the base, i.e., inflationary increases for personnel, supplies, and other expenses may be added in years -08 through -11.

For example:

-07	$1,700,000	
-08	1,400,000	plus increase for personnel, supplies, and other expenses
-09	1,400,000	" " " " " " " "
-10	1,500,000	" " " " " " " "
-11	1,500,000	" " " " " " " "
	$7,500,000	

In "-07 year dollars," the average is $1.5 million.

Renewal applications requesting less than 5 years of support will be limited to an increase of 10 percent per year requested. For example, the ceiling for a 3-year request would be 30 percent higher than the current level.

The maximum ceiling of 50 percent of the current level will apply for the first renewal application submitted by all centers subsequent to the issuance of these guidelines. Thereafter, the following will apply: If the previous renewal application had requested 5 years and was awarded only 3 years as a result of peer review, the next renewal application may request up to 50 percent over the current level if 5 years are again requested. However, if an applicant is awarded 5 years and elects to apply for early renewal, then the ceiling will depend on the number of years that have elapsed. For example, if the application is submitted after 3 years, the ceiling will be 30 percent over the current level.

Ceilings will be discussed with the applicant at the meeting following submission of the Letter of Intent, and the Letter of Certification (see Section 6.3) will specify the ceilings.

8. PROJECT PERIOD

New (Type 1) CCSG applications may request up to 3 years of support, renewal (Type 2) applications up to 5 years. The actual length of project periods will be determined by peer review. If the application is approved for more than 3 years of support, the award of funds recommended for the fourth and fifth years will be contingent on a favorable interim review by an appropriate scientific review group established by NCI. This interim review will not require the submission of a detailed application and usually will not include a site visit evaluation.

9. ALLOWABLE BUDGET ITEMS

Costs are allowable as stipulated in the current DHHS Cost Principles (45 CFR-74) provided they fall into one of the categories discussed below. It is important to recognize that, even though a cost may be allowable, it is the responsibility of the applicant to adequately justify the inclusion and amounts of all items for which funding is requested.

Requested core funds must be in support of the research programs of the cancer center. Since NCI awards other grants that provide comparable costs for cancer control and education, such costs are not allowed on the CCSG. It is strongly recommended that applicants consult with appropriate NCI staff if an item is questionable.

9.1 Professional Personnel Salaries

For all of the categories of personnel listed below, the requested percentage of an individual's salary may not exceed the percentage of effort devoted specifically to the center. Information substantiating this level of effort must be included in the application.

9.1.1 Senior Leadership Personnel

This category includes individuals who have responsibility for overall direction of the entire center. Senior leadership personnel that qualify include: center director, deputy director, associate directors for laboratory and clinical research, and associate director for education. In the last case, salary could be requested for the effort the associate director devotes to coordination and/or direction of the center's research training programs, but not for the effort related to clinical and/or community education activities.

9.1.2 Major Program Directors

Many centers are organized into various identified programs, either along disciplinary lines (such as medical oncology, pharmacology, virology, epidemiology, etc.) or according to organ sites (e.g., colon, lung, prostate, etc.). Such "programs" include research projects conducted by a number of investigators and have designated leaders or program directors.

Program directors or leaders are eligible for salary support under this category for the time and effort they devote to carrying out functions such as research planning, supervision, review of results, publications, and/or grant applications, etc. A description of activities and time estimates for all program directors' functions must be included in the proposal. Program directors will not be funded unless they qualify as staff investigators (see Section 9.1.3) and direct bona fide programs. Program directors may receive additional salary support as staff investigators (see Section 9.1.3) or as supervisors of shared resources (see Section 9.5).

9.1.3 Staff Investigators

Scientists who are members of, or closely identified with, the cancer center and who have peer reviewed research support may receive salary as center staff investigators. To qualify, an individual must either be the designated principal investigator on a research grant or contract or the director of a subproject of a program project grant (P01) or a subproject of

a cooperative clinical research grant (R10). These grants or contracts must have been awarded as a result of creditable external peer review such as by an NIH study section.

A major purpose of this partial support is to provide some of the necessary stability for a "core" of investigators with proven records. The salary support from the CCSG is reimbursement for effort devoted to peer reviewed project(s). Some of the salary support may be for effort devoted to grants and contracts awarded to other principal investigators. The percentage of salary supported by the CCSG may not exceed the percentage of unfunded effort approved by peer review(s) of the individual grant(s) and contract(s). The following table presents various examples for clarification:

(1)	(2)	(1) - (2)
% Effort Approved by Peer Review on Individual Grants and Contracts	% of Effort Funded (Salary) on Individual Grants and Contracts	% of Effort Not Funded, the Maximum That May Be Requested on CCSG
50%	-0-	50%
50%	10%	40%
50%	40%	10%
50%	50%	-0-
20%	10%	10%
20%	20%	-0-
100%	80%	20%
100%	50%	50%

It should be noted that a staff investigator may provide other services to the center, such as supervising a shared resource or service or serving as a major program director. Additional salary support for the time devoted to these activities may be requested under the appropriate category. For example, if a staff investigator is also designated as a major program director, an additional portion of his or her salary could be charged to the CCSG if the activities he/she carries out as program director justify the additional percentage of salary.

Salary support under this section may be used only for the individuals named in the application and approved. If a staff investigator loses peer reviewed support during the approved project period of the CCSG, the center director may provide interim suppport from developmental funds as described in Section 9.2.

Ceilings on requests for staff investigator salaries are as follows.

The special nature of this type of salary support and budgetary constraints require that the amounts requested be limited.

For Renewal Applications:

- If current staff investigator salary support exceeds 25 percent of the direct costs of the present grant, the renewal application may request no more than the current level and must include a plan to phase down to the 25 percent level. The funds made available by phasing down this salary support may not be reallocated for other types of CCSG support. The amounts requested for salaries in the renewal must conform to that plan. The details of this plan will be negotiated with NCI.

- If current staff investigator salary support is less than 25 percent of the present grant, the center may request up to either (a) 25 percent of the direct costs of the current grant, or (b) the current level of staff investigator salary support plus an increase of no more than 10 percent of the ceiling for the renewal application (see examples below), whichever is less.

	(1) Current Level, Total	(2) Current Level, Staff Investigators Salary	(3) Renewal Ceiling	(4) Staff Investigator Ceiling
A.	$500,000	$200,000	$750,000	$200,000, the current staff investigator level*
B.	$600,000	$100,000	$900,000	$150,000, 25% of current grant**
C.	$400,000	$ 20,000	$600,000	$80,000, the current staff investigator salary plus 10% of the renewal ceiling

* Application must include a plan to phase down to 25 percent of current level, or $125,000.

** Less than the total of current staff investigator salaries plus 10 percent of renewal ceiling, which could be $190,000.

For New Applications

No more than 10 percent of the requested funds may be designated for staff investigator salary support.

9.2 Developmental Funds

9.2.1 New Investigator and Program Support

The CCSG may provide for salaries and research costs of investigators at the institution who have not previously received major support and/or for investigators newly recruited from outside the parent institution. Investigators at the applicant institution who qualify are those who have not previously been principal investigators (PI) of an NIH R01 grant or PI of any other type of grant or contract in excess of $37,500 direct costs per year. Newly recruited investigators who have received such support at another institution are eligible provided they do not transfer more than $60,000 of direct costs in grant support when they move to the center.

Although this type of support is designed for individual investigators, it may be used to develop "programs" by providing support for several investigators in the same field. In addition, the mechanism may be used as an aid in recruiting senior scientists or program leaders provided the recruit does not transfer more than $60,000 grant support to the center.

Funds awarded under this section may be used for salary, technical support, laboratory supplies, and equipment up to a maximum of $60,000 per year per investigator. For newly recruited investigators who transfer grant support when they move to the center, developmental funds may supplement their support up to a total of $60,000 per year. For example, if an investigator transferred a grant of $40,000, the investigator would be eligible to receive up to $20,000 under this provision. For each investigator, the duration of support will be limited to 3 years or until the investigator achieves independent funding, whichever comes first. Although the amount per investigator is $60,000 in 1981, the allowable amount may vary in subsequent years and applicants should discuss this with Cancer Centers Branch staff.

9.2.2 Interim Research Support

If a staff investigator's renewal grant or contract application is approved but not awarded because of lack of funds (as opposed to disapproval), the CCSG may provide interim salary and research support for up to 24 months. This support may be provided whether or not some of the salary was funded by the CCSG. In order to identify staff investigators eligible for this interim support, the application must include a listing of all of the center's staff investigators and their grants and contracts with salary support indicated.

A format is provided on page 19 of these guidelines. In addition, the application is to include a description of the procedure used to select these investigators such as the method of identifying membership in the center. The support provided under this section may not exceed $60,000 direct costs per year for 2 years. The intent of this provision is to permit the center director to partially support an investigator who has a reasonable probability of regaining independent research support.

9.2.3 Development of New Shared Resources

Funds provided under this section may be used to develop new center shared resources during the continuation years of the CCSG. Budget requests for existing shared resources or for those that will begin operation during the first year of the grant should be requested under Section 9.5 and not as developmental funds.

Applicants should request and justify funds according to these three categories: (a) new investigator and program support; (b) interim research support; and (c) development of new shared resources.

Peer review of this part of the application will be based upon the soundness of the plan for selection of new investigators, programs, and resources, and the demonstrated record of the center in identifying and appropriately using such funds to further the goals of the center. Specific individuals to be awarded new investigator support need not be identified in the application, nor is it necessary to delineate the specific research to be pursued by these individuals.

After an award is made, the center director may redistribute funds among the categories. It is the intent that developmental funding provide a flexible means for the center director to progress toward achieving the goals of the center. The center should maintain a detailed record of the allocation of developmental funds to facilitate peer review of their use and management.

9.3 Administration

This category includes the costs necessary for the central administration and fiscal management of the center, such as the salary of a chief administrator, secretarial support for senior personnel, grants and fiscal management, etc. Those costs may not duplicate or replace costs included in the institution's indirect cost base.

9.4 Planning and Evaluation

Costs of planning and evaluation are allowable, including costs of an external advisory committee, ad hoc scientific and technical consultants, and consulting firms providing needed experience and/or technical assistance in planning and evaluation for the center.

9.5 Shared Resources and Services

The CCSG may include funds for laboratory and clinical facilities, equipment, and services that will be used by multiple staff for projects or programs supported by peer reviewed grants and/or contracts. Occasional exceptions to this rule may be desirable, such as in the case of a new investigator supported through developmental funds from the CCSG. Logs and records should be maintained to document the usage. Specific examples include large shared equipment items, biostatistics,* animal facilities and services, electron microscope facilities, histology and pathology services, tissue culture, media preparation, instrument shops, glassware washing, libraries, biosafety services, tumor procurement services, biohazard facilities, photography and illustration services, secretarial pools, centralized word processing, research bed units, clinical pharmacology and toxicology, immunology or immunoparameters testing services, clinical trials and protocol offices, special animal colonies, amino acid analysis, HPLC facilities, cell sorting, chemical and drug synthesis labs, NMR facilities, protein chemistry labs, animal radiation facilities, radioisotope facilities, mass spectrometry labs, etc. These types of resources may require partial funding not possible or desirable from individual grants or contracts. Funding by the CCSG may also result in a cost savings to the center.

For such shared resources and services, most of the operating costs are usually not provided by the CCSG. Costs directly identified with individual research projects are usually provided by individual grants or contracts. Applicants are encouraged to maximize funding from these other sources by means of a system of cost allocation, such as charging those using the resource or service. However, it is realized that no single or standard approach will be correct for all types of resources at all centers. Some resources may operate much more efficiently without user charges, while for others it may be best for all costs to be obtained from individual grants and contracts rather than from the core grant. The proper distribution of costs is an

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* The statistical activities of a center can best be carried on if the statistical, epidemiological, and computer components of the center are organized for efficient interaction. In the past, these three activities have been referred to as the Epi-Stat portion of the core grant. As this activity is a centralized shared service, only those portions that are used by a number of investigators should be charged to the core grant. In general, these would be consultation, statistical design and analyses, and center computer needs, including programming. The Centralized Cancer Patient Data System (CCPDS) program is a recognized activity of comprehensive cancer centers. Where the center is participating in the CCPDS program, those charges of a cancer registry nature necessary to CCPDS should be charged to that CCPDS grant.

administrative decision to be made by the center director. Peer reviewers of the CCSG will be asked to evaluate requests for funds for shared resources and services in terms of the need, quality, efficiency and effectiveness of the facility, and the appropriateness of the funds requested for the current and potential users. Reviewers will not make judgments as to whether or not the costs requested should be provided by other grants and contracts through a system of cost allocation.

If a center director decides to request most of the costs of a shared resource on the CCSG, then amounts requested in R01's, P01's, etc., will be obviously less. If 100 percent of the costs are charged to the CCSG, none should be requested in other applications from the center. NCI staff will monitor applications from the center to assure that duplicate funding does not occur. To this end, the CCSG application should contain detailed information concerning any system of cost allocation that has been or will be established for each shared resource.

9.6 Hospitalization and Clinical Research Costs

Grants may be used to pay clinical research costs and supporting services insofar as they are for legitimate items, as described in the previous sections. One obvious example is the cost required to support and staff a clinical research bed unit. Hospitalization and other costs related to specific clinical research programs should be charged to specific research grants and/or contracts.

9.7 Alteration and Renovation

Alteration and renovation of an existing structure to provide suitable facilities in which to conduct the programs of the cancer center may be paid for by the CCSG. The policy of the National Cancer Institute permits up to 100 percent of the costs of alteration and renovation to be charged to a CCSG. The amount budgeted or used for alteration and renovation during a period of three consecutive budget periods (whether or not the 3 years overlap two distinct competitive segments of support) shall not exceed the lesser of $100,000 or 25 percent of the total direct costs reasonably expected to be awarded from Federal funds for that period. For amounts over this figure, application may be made for support under the Research Facilities Construction Program of the National Cancer Institute. Space vacated by personnel moving to space altered or renovated with CCSG funds must come under the control of the center director. As an alternative, the institution, in concurrence with the center director, may make comparable space available for reasons proposed by the institution and acceptable to the NCI. Funds for alteration and renovation should be requested on the appropriate budget page. For example, if the alteration and renovation is for a shared resource, the request should be included in the budget for that resource.

10. SPECIAL INSTRUCTIONS FOR PREPARING CANCER CENTER SUPPORT GRANT APPLICATIONS, NEW AND RENEWAL

This section supplements the standard Instruction Sheet for PHS-398, which is enclosed with application kits. The standard instructions are designed primarily for applications for single research projects. Since the CCSG involves program goals and policies that differ from the conventional research grant, the following format must be followed and all applicable items included:

I. Table of contents

II. Letter of Certification from the Cancer Centers Branch

III. Overall and individual CCSG budgets. Include all budget requests here and under Part VIII. Narrative justifications are to be included in Part VIII of the application.

IV. Description of activities that justify consideration as a cancer center. Specifically address all items under Section 5, Essential Characteristics of Cancer Centers, of these guidelines.

V. Brief background of the applicant institution:

- A. Historical
- B. Physical facilities
- C. Teaching activities
- D. Overall budget for research and training showing percentage related to cancer
- E. Overall budget for clinical service showing percentage related to cancer
- F. Location of neighboring institutions and affiliation.

VI. Standard center information -- Each cancer center applying for a new or renewal CCSG must include in the application data related to the funded projects (grants and contracts) included in the cancer center program, data regarding cancer patients seen at the institution, cancer center members, etc. A format for presentation of these data will be provided to applicants at the meeting following submission of the Letter of Intent. New and renewal applications must contain the data in the proper format. Centers with funded CCSG's will be required to furnish such data to the Cancer Centers Branch annually before continuation grants are awarded.

VII. Description of programs and plans for continuation or development of the cancer center. This section should include a description of the programs of the center and how they will be further developed and coordinated. The following elements should be included:

A. Description and plan for individual program areas, including a narrative describing each program in laboratory and clinical research. For each program, summarize in the form of a table and then list current and pending component funding using project titles in the listings provided under Part VI. Indicate the staff positions associated with the program area and indicate any steps to augment the staff. In describing each of these program areas, it is important to relate how the program will benefit from inclusion in the center, and particularly from funds requested in the CCSG application.

B. Organization and administration of the center -- This section of the application should define organizational arrangements for the center and specify the current degree of authority of the center administration in terms of space allocation, staff appointments, preparation of budget, control of expenditures, etc. Indicate the degree of autonomy and include letters of agreement with officials who concurred in this decision. Describe the criteria and procedures for appointment of center members. Include charts showing the administrative setting within which the center exists and the organization of the center per se.

C. Describe the methods used for program evaluation, planning, management practices, etc.

D. Future operating levels and sources of support. Give estimated dollar levels of required operating costs of the entire center for each of the next 3 years in the case of a new application, and for each of 5 years for a renewal application. Include expected sources of support and estimated percentages of support expected to be contributed by each source.

VIII. Presentation of the CCSG budgets -- Separate detailed budgets should be prepared according to the following guidelines. Each separate budget should be prepared using the budget pages from the PHS-398 application form for both the first 12-month period and estimates for all years, and must be followed by a narrative fully justifying the funds requested.

If the grant application includes costs or activities that involve institutions other than the sponsoring organization, the application is considered to be for a consortium effort. Such cooperative activities may be included in a core grant application, but it is imperative that a consortium application be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. The published policy governing consortia is available in the business offices of institutions that are eligible to receive Federal grants-in-aid. Consult the latest

published policy governing consortia before developing the application. If clarification of the policy is needed, contact the staff of the Grants Administration Branch, NCI.

A. Professional personnel -- The first three separate budgets in the CCSG application should request salary support for (1) senior leadership personnel, (2) major program directors, and (3) staff investigators, if requested. The narrative justification for the salaries for the professional personnel should fully describe the duties the salaried individuals will be performing for the center.

Requests for salaries for staff investigators should include a statement describing how such staff investigators were selected together with a table in the following format showing each investigator's effort and salary support on all grants and/or contracts. When the staff investigator's effort is on a grant or contract on which the investigator is not the principal investigator (PI), please give the name of the designated PI and the grant/contract number.

Name	Grant or Contract	Peer-Reviewed Effort	% of Recommended Salary	% Salary Requested on CCSG
Doe, J.	R01-CA-1234-01	40%	20%	20%
	R01-CA-2345-02	30%	30%	-0-
Smith, J.	R01-CA-6789-01	10%	10%	-0-
	N01-CP-1256-01	30%	-0-	30%

B. Administration -- The next budget should present the request for the administration for the center. Again, the duties the salaried individuals will be performing for the cancer center should be fully described.

C. Planning and evaluation -- A separate budget and narrative should be developed for any request for the costs of planning and evaluation.

D. Shared resources and services -- A separate budget and narrative should be prepared for <u>each</u> resource or service for which funds are requested. On the budget form, indicate the costs requested for the personnel, equipment, supplies, etc., for that resource or service.

The narrative in support of the request for a shared resource or service should describe the resource or service, its scientific purpose or necessity, and should list those programs, projects, and investigators who will be using the resource or service. The application should also indicate any grant or contract support for the programs and projects that will be using the resource or service. At the time of the site visit, user logs or similar information should be available to validate extent of use and degree of sharing. For each shared resource or service, a narrative should describe any system, operative or planned, by which costs are to be allocated to individual grants and/or contracts. The total operational budget for each resource should be provided with an indication as to percentage of support to be obtained from the CCSG.

E. Developmental funds -- Prepare a separate budget for each of the following:

1. New investigator and program support -- Indicate number requested. Prepare budget indicating salary, technical support, supplies, and equipment with the total not to exceed $60,000 per investigator. A narrative statement should justify the number requested in terms of (a) anticipated turnover and (b) planned expansion and should detail the mechanism for selection of those to be supported. In renewal applications, the narrative must specify what has happened to each previously funded new investigator. In new applications, the narrative should provide any information that reviewers can use to estimate the probability that new investigators, if supported by the CCSG, will be successful in acquiring independent support.

2. Interim research support -- Include and explain any request for interim support needed for investigators who may lose salary because renewal grant applications are not funded. Include a listing using the format described earlier to identify eligible investigators.

3. Development of new shared resources -- Explain and justify any request for support of <u>new</u> shared resources in continuation years.

IX. Overall budget for CCSG -- Forms to be obtained from the Cancer Centers Branch.

Prepare collated budget tabulations using the form that will be provided at the meeting following submission of the Letter of Intent. In addition, a separate budget Form NIH-398 should

be prepared using the total figures for personnel, consultants, equipment, supplies, etc., and should be included as page 3 of the application as indicated in the instructions accompanying Form PHS-398. This page is to be followed by page 4 of Form PHS-398 giving total budget estimates for all years of support requested.

X. Replacement of existing support -- Fully describe all instances in which any type of existing support would be replaced by the CCSG request.

XI. Biographical sketches of professional personnel -- Using the format in Form PHS-398, furnish biographical sketches for all professional personnel who are members of or who are associated with the cancer center. These should be presented alphabetically. The individual biographical sketches should, as indicated in the Form PHS-398, include the current and pending grant and/or contract support as well as all or a selection of the most representative publications.

11. GRANT REVIEW PROCEDURES APPLICABLE TO A CANCER CENTER SUPPORT GRANT

Applications for a Cancer Center Support Grant undergo competitive peer review. All grant applications submitted to NIH are received by the Division of Research Grants (DRG). Applications not in the format specified in Section 10 will not be reviewed.

After receipt by DRG, Cancer Center Support Grant applications customarily are referred to the Cancer Center Support Grant Review Committee which is administered by the Grants Review Branch. Upon receipt of the application, NCI review staff usually will arrange a site visit. The findings of the site visit team are provided to the parent review committee during its consideration of the application. The recommendations of the committee and the priority score voted (if approved) are presented to the National Cancer Advisory Board (NCAB) for final review and recommendation to NCI. Final funding decisions are then made by NCI for those applications recommended for approval by the NCAB.

12. REVIEW CRITERIA

The following review criteria are used when applicable (not necessarily in order of importance):

- Degree of interdisciplinary coordination
- Adequacy of organizational capability and facilities
- Qualifications and authority of center director

- Adequacy of the commitment of the parent institution
- Impact of the center on the consolidation and/or focus of cancer-related research activities
- Mechanisms for evaluation of programs, personnel, and developmental funds requests
- Need for, and quality of, requested shared resources and services
- Need for, and quality of, personnel for whom funds are requested
- Need for developmental funds requested.

13. NEGOTIATION AND AWARD

Applications recommended for approval by the National Cancer Advisory Board and selected for funding will be negotiated by NCI staff. In light of the necessity to impose limits on the amounts that can be requested (see Section 7), the NCI desires to maximize the flexibility available to centers in the utilization of the funds provided. The center director will be required to submit noncompeting (Type 5) budget requests each year before an award is issued. Although these budgets usually will closely conform to the recommendations of the peer reviewers, a center director may decide to propose budgets different from those recommended. Generally, such changes will be permitted provided the proposed expenditures are not in support of areas specifically disapproved by peer review, are justified in the noncompeting (Type 5) application, and are allowable costs under these guidelines. Significant changes will be brought to the attention of the reviewers of the next renewal (Type 2) application.

14. REPORTING REQUIREMENTS (ANNUAL REPORT)

After a grant is awarded, an annual Summary Progress Report on the achievements attributable to CCSG must be submitted as well as an expenditures report.

Special reporting requirements may be necessary from time to time to assist in documenting the extent to which the cancer center is contributing to the fulfillment of objectives of the National Cancer Program.

15. PUBLICATIONS

All publications that were supported in any manner from the Cancer Center Support Grant must cite the grant as a contributing source of support using the following phraseology: "This investigation was supported by NIH Research Grant Number _____ from the National Cancer Institute."

In addition, each center must maintain a current and complete bibliography of center-related publications for inclusion in the annual report, listed alphabetically by first author, and catalogued by calendar year in which they were published. Abstracts may be listed separately.

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